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**Datasheet for the decision
of 16 October 2014**

Case Number: T 2614/11 - 3.3.07

Application Number: 04770702.1

Publication Number: 1713448

IPC: A61K9/16, A23L1/30

Language of the proceedings: EN

Title of invention:

STABLE BEADLETS OF LIPOPHILIC NUTRIENTS

Patent Proprietor:

OmniActive Health Technologies Pvt. Ltd

Opponent:

DSM Nutritional Products Ltd

Headword:

STABLE BEADLETS OF LIPOPHILIC NUTRIENTS/Omniactive Health
Technologies

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - (no)
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Decisions cited:

T 0020/81

Catchword:



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Boards of Appeal
Chambres de recours**

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Case Number: T 2614/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 16 October 2014

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
20 October 2011 concerning maintenance of the
European Patent No. 1713448 in amended form.**

Composition of the Board:

Chairman J. Riolo
Members: D. Boulois
M.-B. Tardo-Dino

Summary of Facts and Submissions

- I. European patent No. 1 713 448 B1 based on application No. 04 770 702.1 was granted on the basis of a set of 47 claims.
- II. An opposition was filed under Article 100 (a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, the patent was not sufficiently disclosed, and its subject-matter extended beyond the content of the earlier application as filed.
- III. The documents cited during the opposition and appeal proceeding included the following:
- (1): Hoffmann-La Roche AG, "Produktformen-Vitamine und Carotinoide", März 2000
 - (2): WO 00/27362 A1
 - (3): WO 2004/080199 A2
 - (4): EP 0 229 652 A2
 - (5): "NON-PAREIL SEEDS", JRS Pharma LP, März 2003
 - (7): Brochure "ROVIMIX® E-50 Adsorbate and SD", F. Hoffmann-La Roche Ltd, published in 1990
 - (8): Brochure "The new ROVIMIX® E-50 Adsorbate makes vitamin E nutrition easier", Roche, Basel, published Sept. 1995
 - (9): Römpf, Lexikon der Chemie, Adsorptio, 10. Auflage, Stuttgart, 1996, Page 67, Sept. 1995
- IV. The present appeal lies from the decision of the opposition division to maintain the patent as amended. The decision was based on the set of claims filed during the oral proceedings of 13 September 2011 as main request.

Independent claim 1 of the main request read as follows:

"1. Beadlets of lipophilic nutrients comprising an inert spherical core and a coating comprising stabilizing antioxidant and lipophilic nutrient, formed from a colloidal suspension of said lipophilic nutrient and of said antioxidant by diluting a solution of said lipophilic nutrient in a non-polar solvent with a polar solvent and by subjecting the colloidal suspension to fluidization using a fluidized bed system employing said inert core."

Claim 19 of the main request was a process claim.

- V. In the decision under appeal, the opposition division considered that the objections to the process claims 19-47 had not been substantiated during the opposition procedure, therefore the opposition was considered to be deemed inadmissible insofar the subject-matter of these claims was concerned.

The subject-matter of claim 1 of the main request found a support in paragraphs [0023], [0024] and [0043] and thus met the requirements of Article 123(2) EPC.

The contested patent included nine examples falling under the scope of claim 1, and provided lists of suitable lipophilic nutrients (cf. par. [0033] and [0034]), stabilising antioxidants (cf. par. [0041]) and inert cores (cf. par. [0031]). The claimed invention was thus sufficiently disclosed.

In the absence of any clear and unambiguous disclosure of a coating of vitamin E on the core particles in documents (1) and (2) and of a coating of a lipophilic nutrient on the core particles in document (3), these documents were not novelty destroying against claim 1 of the main request.

As document (4) disclosed coated particles product with carrier particles forming the coating and tocopherol and antioxidant forming the core, this document was not novelty-destroying with respect to claim 1 of the main request.

As regards inventive step, the problem to be solved by the claimed invention was the provision of nutrient beadlets which were stabilised against oxidation and in free-flowing form.

Document (4) addressed the same problem and disclosed a vitamin E powder comprising tocopherol, which is a lipophilic nutrient, a carrier, and an antioxidant. The examples of the contested patent showed a surprising effect in respect of the free-flowing properties.

The skilled person would not have had any motivation to adapt the teaching of document (4), alone or in combination of the teaching of documents (1)-(3) or (5), thereby arriving at the solution to the problem provided in claim 1 of the main request, which was considered to involve an inventive step.

VI. The opponent (appellant) filed an appeal against said decision.

With the statement setting out the grounds of appeal the appellant submitted the following pieces of evidence:

(12): Report 12-00024-20120215 "Visualization and mapping of chemical elements of Rovimix® E-50 Adsorbate", Solvias AG, Kaiseraugst, 15 Feb. 2012.

VII. With a letter dated 28 June 2012, the proprietor (respondent) filed a new main request and auxiliary requests 1 to 4.

VIII. A Board's communication dated 24 September 2014 was sent to the parties.

It stated in particular that the process claims did not form part of the opposition and that document (3) was novelty-destroying for claim 1 of the main request under Article 54(3) EPC.

As regards inventive step, the Board noted also that no comparison had been made with the prior art compositions.

IX. With a letter dated 9 October 2014, the respondent filed a main request and auxiliary requests 1 to 3 corresponding respectively to the auxiliary requests 1-4 filed previously with letter dated 28 June 2012.

The subject-matter of the independent claims 1 of the requests read as follows, the difference(s) compared with the main request maintained by the opposition division shown in bold:

(a) Main request

"1. Beadlets of lipophilic nutrients comprising an inert spherical core and a coating comprising a stabilizing antioxidant and lipophilic nutrient, formed from a colloidal suspension of said lipophilic nutrient and of said antioxidant by diluting a solution of said lipophilic nutrient in a non-polar solvent with a polar solvent and by subjecting the colloidal suspension to fluidization using a fluidized bed system employing said inert core, **resulting in the formation of inert cores uniformly coated with the lipophilic nutrient in the form of uniformly spherical beadlets.**"

(b) Auxiliary request 1

"1. Beadlets of lipophilic nutrients comprising an inert spherical core and a coating comprising a stabilizing antioxidant and lipophilic nutrient and **a binding agent**, formed from a colloidal suspension of said lipophilic nutrient and of said antioxidant by diluting a solution of said lipophilic nutrient in a non-polar solvent with a polar solvent and by subjecting the colloidal suspension to fluidization using a fluidized bed system employing said inert core, **resulting in the formation of inert cores uniformly coated with the lipophilic nutrient in the form of uniformly spherical beadlets.**"

a) Auxiliary request 2

"1. Beadlets of lipophilic nutrients comprising an inert spherical core **comprising a carbohydrate that does not react with the lipophilic nutrient, said carbohydrate comprising a carbohydrate selected from the group consisting of sugar, mannitol, starch, sago, and microcrystalline cellulose**, and a coating comprising a stabilizing antioxidant a lipophilic nutrient and **a binding agent**, formed from a colloidal suspension of said lipophilic nutrient and of said antioxidant by diluting a solution of said lipophilic nutrient in a non-polar solvent with a polar solvent and by subjecting the colloidal suspension to fluidization using a fluidized bed system employing said inert core, **resulting in the formation of inert cores uniformly coated with the lipophilic nutrient in the form of uniformly spherical beadlets.**"

b) Auxiliary request 3

The subject-matter of claim 1 of auxiliary request 3 corresponds to the process claim 19 as granted or as maintained by the opposition division:

"1. A process for the preparation of beadlets of lipophilic nutrients comprising:
(i) forming a colloidal suspension of lipophilic nutrient by dissolving the lipophilic nutrient in a non-polar solvent and diluting the resulting solution with a polar solvent;
(ii) spraying the resulting colloidal suspension onto an inert core in a fluid-bed system provided with a bottom-spray mechanism at a temperature in the range of ambient temperature to 45 degree C, at an atomisation pressure in the range of about 0.1 kg/cm² to about 3 kg/cm² and a spray rate in the range of about 10 g/hour to about 600g/hour; and
(iii) drying the resulting beadlets in the fluid-bed system at an atomisation pressure of about 0.8 kg/cm² to about 1.2 kg/cm²."

X. Oral proceedings took place on 16 October 2014.

XI. The arguments of the appellant may be summarized as follows:

Documents (1), (2), (3), (7) and (8) were considered as potential closest prior arts.

Document (12) showed that the silica particles of documents (1), (7) and (8) were spherical and covered by tocopherol.

As to the "*inert spherical core*", it was considered that silica was as inert as the excipient used for the beadlets in the contested patent. All the listed excipients had also interactive functions with the lipophilic nutrient.

The examples of the contested patent could not be taken in account for the assessment of an effect, since the beadlets were made from sugar seeds and comprised two further coatings. It had not been showed in particular that beadlets without coating might have good angles of repose and flowing properties.

The problem had to be reformulated as the provision of further beadlets.

The claimed solution was obvious, especially in view of document (5), which disclosed the use of non-pareils.

A particular effect linked with the use of a binding agent had not been shown in the contested patent. The subject-matter of claim 1 of auxiliary request 1 was therefore not inventive.

As regards the subject-matter of claim 1 of auxiliary request 2, the restriction did not exclude the use of excipients, such as carbohydrates, presenting porous character. It could not be considered to be inventive. Moreover, document (4) mentioned also the use of carbohydrates.

As regards the process claim of auxiliary request 3, this claim was part of the opposition formed. Objections on lack of disclosure against terms such as "*lipophilic nutrients*" or "*inert core*" in claim 1 as granted were indeed raised in the notice of opposition. These objections had to be extended to said terms also present in the process claims as granted. *De facto*, the extent of the opposition also comprised the process claims.

XII. The arguments of the respondent may be summarized as follows:

The problem of the patent was the provision of beadlets which provide physical characteristics, such as spherical, free-flowing beadlets suitable for tableting (see par. [0014] to [0017]).

As document (3) was published after the priority date of the contested patent, it was not relevant for inventive step.

The combination of documents (1), (2), (7) or (8) with the content of document (5) was not relevant for the inventive step of the main request.

Moreover, the beadlets produced in document (4) were not appropriate for making tablets and anyway could not be compressed to tablets.

There was thus a technical prejudice for making beadlets suitable for being compressed into tablets. This particular technical problem was unknown from the prior art and constituted therefore a newly identified problem, namely a problem-invention.

Moreover, the term "*inert spherical core*" excluded silica, which interacted with tocopherol in document (4). The active agent is indeed sucked by the silica particles and no coating can be formed.

The free-flowing property of the beadlets was demonstrated in example 9 by the calculation of the angle of repose, which was comprised between 23 and 25 degrees for compositions according to the invention, and example 9 showed further the excellent friability, disintegration and dissolution properties of tablet obtained through the compression of the claimed beadlets.

As regards claim 1 of auxiliary request 1, the addition of a binding agent in the coating layer enhanced the efficiency of the coating (see par. [0052]). The binder

had an effect on the friability of the tablets, and did not impair the disintegration rate.

The subject of claim 1 of auxiliary request 2 comprised a further restriction and definition regarding the nature of the inert spherical core.

As regards the subject-matter of auxiliary request 3, it concerned only process claims which have not been discussed in the opposition and were not dealt with in the decision of the opposition division. The process claims should therefore also not be considered in the appeal phase.

XIII. Requests

The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No.1713448 be revoked in its entirety.

The respondent (patent proprietor) requested that the patent be maintained on the basis of the main request or one of the three auxiliary requests, all as submitted with the letter of 9 October 2014. It further requested that the decision of the opposition division to declare the opposition unsubstantiated to the extent that it was directed against the process claims (19-47) be upheld and the process claims be declared outside of the scope of the appeal.

Reasons for the Decision

1. Main request - Inventive step

1.1 The invention relates to stable and usable formulations of lipophilic nutrients in the form of beadlets comprising an inert spherical core and a coating comprising a stabilizing antioxidant and said lipophilic nutrient.

The beadlets ensure stability of the lipophilic nutrient when formulated in the beadlet form itself, or when formulated in tablets. Moreover, said beadlets, which are obtained by a process of fluidized bed, are spherical, free flowing and suitable for tableting or capsule filling (see par. [0001] and [0015]).

1.2 Documents (1), (2), (3), (4), (7) and (8) were considered as potential closest prior arts by the parties.

(a) Documents (1), (7) or (8) relate all to the same commercial product, namely Rovimix® E-50 Adsorbate. Document (7) shows in particular that this product consists of a lipophilic nutrient, namely DL-alpha-tocopheryl acetate, adsorbed on the surface of spherical silicic acid particles, without antioxidant (see document (7), first page). The external layer of DL-alpha-tocopheryl acetate covers furthermore only partially the spherical silicic acid particles, as shown by the experiments of document (12) (see document (12), point 5.2).

Document (8) mentions further the good flowability of the Rovimix® E-50 Adsorbate powder as expressed by an angle of repose of the beadlets of 30° (see document (8), "Flowability").

(b) Document (2) relates to a method of producing dry, free-flowing mixtures of vitamin powders, obtained in the examples by high speed mixing of a

tocopherols blend with silica. This document does not give further indications on the final structure obtained by said process.

(c) The date of publication of document (3) was posterior to the priority date of the contested patent, and this document is thus not relevant for the assessment of inventive step.

(d) Document (4) discloses the preparation of granulates by spray drying a carrier, tocopherol and a stabilizing agent to stabilize the potency of the tocopherol in the composition (see page 3, lines 9-12). The stabilizing agent is chosen among known antioxidants, namely ascorbic acid, citric acid, cysteine or methionine (see page 3, lines 22-27).

The process of preparation consists in forming an emulsion or slurry of all components followed by spray drying (see page 3, lines 40-44). The result of the spray-drying process is a composition in the form of a stabilized powder with a carrier supporting the tocopherol.

Document (4) further discloses in its examples the preparation of particulates by coating of tocopherol and an antioxidant onto silica gel by using a laboratory evaporator and a drying step (see for instance example 1). This document does not give more details on the structure of the particulates obtained by the method of the example, in particular if this coating was complete and uniform.

The document (4) is the document presenting the most common technical features with the subject-matter of claim 1. The subject-matter of claim 1 of the main

request differ indeed from the compositions disclosed in document (4) only by the structure, namely an uniform layered structure in claim 1 of the main request instead of a granulate structure or a non uniform layered coated structure in document (4). Consequently, document (4) is seen as the closest prior art.

- 1.3 The problem as set out in the description of the contested patent may be seen in the provision of beadlets with excellent free flowing properties which are appropriate for making tablets (see par. [0015], [0028]).
- 1.4 As a solution to this alleged problem, claim 1 of the main request proposes beadlets comprising an inert spherical core and a uniform coating comprising a stabilizing antioxydant and a lipophilic nutrient, formed from a colloidal suspension of said lipophilic nutrient and of said antioxidant by diluting a solution of said lipophilic nutrient in a non-polar solvent with a polar solvent and by subjecting the colloidal suspension to fluidisation using a fluidised bed system employing said inert core.
- 1.5 It has to be investigated whether there is sufficient evidence supporting the alleged effect.
 - 1.5.1 The patent in suit provides 9 examples of compositions, all made from non-pareil sugar seeds uniformly and completely coated with a layer of a lipophilic nutrient and an antioxidant. The loaded non-pareil seeds were further coated by two protective layers acting as oxygen and moisture barrier (see par. [0039]-[0040]), such as in examples 1-8 by a first layer comprising essentially ethyl cellulose and hydroxypropyl methyl

cellulose and a second layer comprising essentially sodium carboxymethyl cellulose or polyvinyl alcohol. The flow property of the beadlets was assessed in example 9 by determining the angle of repose which was comprised between 23 and 25 degrees (see par. [0101]). The tablets obtained with the beadlets showed good properties, namely disintegration times of less than 2 minutes and friabilities of less than 1% (see par. 0102] and Table 1 of example 9).

1.5.2 The examples of the contested patent show undoubtedly an effect linked to the specific beadlets disclosed therein, an effect whose merits would deserve to be rewarded.

Said effect shown in the examples can however not be taken in consideration in the assessment of inventive step of the invention as claimed for following reasons:

(a) First, the specific compositions of the examples of the contested patent are not representative of the claimed object.

Said compositions of the examples have indeed their inert spherical core made from non-pareil sugar seeds, which structure and properties are particular and not necessarily shared by any "*inert spherical core*" in general.

The term "*inert spherical core*" of claim 1 of the main request is not limited to sugar non-pareil seeds and encompasses indeed any kind of carrier, including porous inert carriers, such as those of document (4) made from porous silica.

Moreover, the compositions of the examples present two further external coating layers which may have an essential impact on the effect observed and which are absent from the subject-matter of claim 1.

The effect observed with the compositions of the examples of the contested patent cannot thus be extrapolated to the whole subject-matter of claim 1.

- (b) Secondly, the examples of the contested patent do not provide a comparison between the compositions according to present invention and compositions according to document (4), in particular regarding the flowability of the powders or the properties of tablets obtained with the beadlets.

According to the case law of the boards of appeal, alleged advantages to which the patent proprietor merely refers, without offering sufficient evidence to support the comparison with the closest prior art, cannot be taken into consideration in determining the problem underlying the invention and therefore in assessing inventive step (see for instance T 20/81). Said technical effect must be established in a plausible way over the closest state of the art.

The board does not see any reason to deviate from this case law as it was based on the understandable rule that a patent can only properly be granted for a solution claimed as non-obvious if it actually has the alleged effect.

- 1.5.3 It is thus not possible to conclude to the existence of an improvement over the prior art.

- 1.6 Consequently, in the absence of any experimental evidence or arguments establishing a minimum plausibility, the presence of an improvement of the flowability and tableting properties of the claimed beadlets over the beadlets of document (4) has not been

credibly demonstrated and the technical problem must be reformulated as the provision of alternative beadlets.

In view of the information found in the examples of the contested patent, the board is convinced that the problem has been plausibly solved.

- 1.7 Since the problem consists the provision of alternative beadlets, it belongs to the skilled person to modify the existing beadlets as part of its normal activity.

The production of uniformly coated beadlets is commonly known by the skilled person and the process of fluidized bed is an applicable method known in the art to produce such coated product.

The production of beadlets with an uniform coating can only be seen as an arbitrary choice that would be made as a matter of routine by a skilled person.

- 1.8 Further arguments from the respondent

- 1.8.1 The respondent argued that the problem of the provision of beadlets which are appropriate for making tablets was neither known nor deductible from any cited prior art document. It constituted therefore a newly identified problem, namely a problem-invention, which the skilled person would not have tried to solve.

Moreover, according to the appellant, beadlets formed from silica particles are not capable to provide powders with good flowability properties; the beadlets of the invention offered thus in any case an advantage over the prior art, which related only to silica particles.

Said silica particles could also not be classified as inert and spherical.

1.8.2 The Board could not share this opinion.

It is true that the discovery of an unrecognised problem may in certain circumstances give rise to patentable subject-matter in spite of the fact that the claimed solution is retrospectively banal and in itself obvious ("problem-inventions").

The need for the provision of free-flowing particulates is however already known from document (4) which mentions this property (see page 2, lines 7-9; page 3, lines 9-12). Document (4) mentions in particular the unsuitability of the tocopherol and their esters for certain pharmaceutical applications, "*particularly those in which a powder is required, such as in tablets or capsules*" (see page 2, lines 15-17). It follows that the problems of powder flowability and tableting are related and intrinsically linked together, and as such recognized in the prior art.

Under these circumstances the arguments of the respondent appellant that the claimed invention was inventive since the problem was unrecognized before are not relevant.

As to the argument of the respondent regarding the poor flowability generally obtainable with powders made from inert cores of porous silica, it has not been substantiated or evidenced by the respondent.

This argument is furthermore not credible in view of the angle of repose obtained with porous silica for the product Rovimix® E-50 Adsorbate, showing namely an angle of repose of 30 degree (see document (8), "Flowability tests"), which is similar to the goal of the present invention to provide powders with an angle of repose between 20 and 30 degrees (see par. [0035]), This argument thus cannot form the basis of a

comparison between the compositions of the present invention and composition according to document (4) having also porous silica as inert carrier.

As to the spherical aspect of silica particles, the general sphericity of silica particles was demonstrated by the pictures or drawings of documents (1), (7), (8) or (12) and was confirmed by the measurement of the angle of repose given in document (8).

Moreover, silica is a common excipient and as such has to be considered as inert. On a chemical point of view, it is obvious that silica is as at least as inert as the preferred excipients used in the contested patent, namely sugar, mannitol, starch, sago, and microcrystalline cellulose (see par. [0031]).

- 1.9 Thus, the subject-matter of claim 1 of the main request is obvious vis-à-vis document (4).
Consequently, the main request does not meet the requirements of Article 56 EPC.

2. *Auxiliary request 1 - Inventive step*

The subject-matter of claim 1 of auxiliary request 1 has been amended by the further presence of "*a binding agent*" in the coating.

According to the appellant of the contested patent, the binding agents are added for enhancing the efficiency of the coating, involving a positive effect on the friability of the tablets obtainable and not impairing the disintegration rate of said tablets obtainable from the beadlets (see par. [0052]).

An effect linked with the binder has however not been shown in the examples of the contested patent and is thus not credibly demonstrated. As for the main request

the technical problem must be reformulated as the provision of alternative beadlets.

The use of a binding agent is commonly known by the skilled person and can only be seen as an arbitrary choice that would be made as a matter of routine by a skilled person.

The subject-matter of claim 1 of the auxiliary request 1 is not inventive over document (4). Consequently, auxiliary request 1 does not meet the requirements of Article 56 EPC.

3. *Auxiliary request 2 - Inventive step*

The subject-matter of claim 1 of auxiliary request 2 has been restricted by the feature regarding the inert spherical core namely "*comprising a carbohydrate that does not react with the lipophilic nutrient, said carbohydrate comprising a carbohydrate selected from the group consisting of sugar, mannitol, starch, sago, and microcrystalline cellulose*".

This feature does not constitute a further distinction over the prior art. Although document (4) indeed discloses as preferred carrier carrier silica, it also teaches that alternative carriers might be starch or sugar (see page 3, lines 28-33). The solution was therefore known and taught in document (4).

The subject-matter of claim 1 of the auxiliary request 2 is not inventive over document (4). Consequently, the auxiliary request 2 does not meet the requirements of Article 56 EPC.

4. *Auxiliary request 3 - Admissibility of the appeal*

The subject-matter of the process claims 1-29 of auxiliary request 3 corresponds to the process claims 19-47 of the request maintained by the opposition division or of the claims as granted.

The statement of grounds of appeal of the appellant-opponent contains objections regarding insufficient disclosure against the invention claimed in claim 19 of the request maintained by the opposition division, as well as objections regarding inventive step of process claims 19-47 as maintained by the opposition division.

The subject-matter of the process claims 19-47 as maintained or granted did however not form part of the opposition, which was limited to the product claims 1-18 as granted, as correctly decided by the opposition division.

Although the opposition had been filed on the grounds of Articles 100(a) and (b) EPC against the patent as a whole, the statement of grounds of opposition contained indeed objections and arguments relating exclusively to the product claims 1-18 as granted.

None of the subsequent mail of the opponent, namely the responses of the opponent to the summons to oral proceedings before the opposition division and to the letter of the patent proprietor, which both mentioned the point of the admissibility of the opposition against the process claims 19-47, contained further comments or arguments than those relating to the product claims 1-18.

The opposition was thus found inadmissible by the opposition division insofar the subject-matter of the process claims 19-47 claims as granted was concerned.

There is thus no reason to deviate from the decision of the opposition division. The appeal proceedings accordingly are limited to the product claims, as was the opposition and the appealed decision. The argument of the appellant that the mere objection on lack of disclosure raised in the statement of grounds of opposition against some terms of claim 1 as granted, such as "*lipophilic nutrient*" or "*inert core*" could form a basis for the extent of the opposition to the process claims 19-47, since said terms were also present in claim 19, cannot be accepted. The mentioned objections were indeed explicitly directed to the independent product claim 1, and thus the examination of the opposition was limited by the extent to which the patent was opposed.

As the subject-matter of the process claims 19-47 as maintained by the opposition or as granted does not form part of the opposition, the case is remitted to the department of first instance on the basis of the third auxiliary request which corresponds to said claims 19-47.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the third auxiliary request as submitted with the letter of 9 October 2014 and a description to be adapted thereto.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated